SCHEMA – PROTOCOL M

TITLE: A phase IIb safety and effectiveness trial of two vaginal microbicide gels for the prevention of HIV infection in women

DESIGN: Four arm randomized, controlled trial comparing two microbicides with a placebo and with no treatment. The three arms with study gels will be double-blinded.

POPULATION: Sexually active HIV-uninfected women.

DURATION: 30 months. All participants followed to common study closeout.

PRIMARY OBJECTIVE(S): To evaluate the safety of each vaginal microbicide used in the trial.

To evaluate the effectiveness of each vaginal microbicide used in the trial.

SECONDARY OBJECTIVES: To assess the acceptability of each vaginal microbicide used in the trial.

SCHEDULE OF EVALUATIONS FOR THE FIRST TWELVE MONTHS - PROTOCOL M

PROCEDURES	SCREEN	ENROLL	1	2	3	4	5	6	7	8	9	10	12	d/c
Obtain informed consent	x	x												
Behavioral eligibility	x													
Determine HIV status	x					x				x			x	x
HIV/STD risk reduction counseling	x					x				x			x	x
Behavioral risk assessment		x				x				x			x	x
Medical and menstrual history, physical exam			x	x	x	x	x	x	x	x	x	x	x	x
Pelvic exam						x				x			x	x
Pelvic exam: vaginal pH						x				x			x	x
Pelvic exam : pap smear						x				x			x	x
Pelvic exam : dried smear for gram stain/BV						x				x			x	x
Wet mount (Bacterial vaginosis)						x				x			x	x
Wet mount (Candidiasis)						x				x			x	x
Wet mount (Trichomoniasis)						x				x			x	x
Pregnancy test	x		x	x	x	x	x	x	x	x	x	x	x	x
SDA urine for chlamydia and gonorrhea	x												x	x
Hematology	x					x				x			x	x
Chemistry panel	x					x				x			x	x
Coagulation tests	x					x				x			x	x
RPR	x												x	x
HSV 2 serology		x				x				x			x	x
Adherence assessment		x				x				x			x	x
Social harms assessment		x				x				x			x	x
Acceptability assessment		x				x				x			x	x
Unblinding assessment													x	